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Attorney Docket No. 25645

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

T. NEWMARK et al.

Serial No.: 10/058,299 Group Art Unit: 1617

Filed: January 30, 2002 Examiner: S. Jiang

For: COMPOSITION AND METHOD FOR SMOKE DETOXIFICATION

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

NOW COMES the undersigned and declare that:

1. I, Dr. Karl-Werner Quirin, am a citizen of Germany.
2. That I hold a doctor's degree conferred upon me in chemistry by the University of Saarland, Germany.
3. That I am employed as a head of development and research and CEO for Flavex Naturextrakte GmbH ("Flavex"), Nordstrasse 7, 66780 Rehlingen, Germany. I have worked for Flavex in the field of herbal extraction for 18 years.
4. That during my employment at Flavex, I have been involved

in technology that relates to the development of supercritical herbal extractions.

5. That I have reviewed claim 1 of U.S. Patent Application Serial No. 10/058,299 (the captioned U.S. patent application) and understand that the claim is drawn to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric.

6. That I have reviewed U.S. Patent No. 5,861,415 to Majeed et al. ("the '415 patent"). The '415 patent is related to a process for the extraction of curcuminoids, with curcuminoids meaning a combination of curcumin, demethoxycurcumin, and bisdemethoxycurcumin, as indicated in column 2, lines 5-15 of the '415 patent.

7. That supercritical-CO₂ extraction and hydroalcohol extraction result in two different extracts. Supercritical CO₂ is a non-polar, lipophilic solvent, whereas alcohol plus water results in a polar, hydrophilic solvent. Thus, extraction by supercritical CO₂ results in an extract that contains mainly oily constituents, while extraction by hydroalcohol results in a hydrophilic extract.

8. That about 70% of the supercritical extract is steam volatile oily terpenes. Of the terpenes, about 80% are turmerone isomers, which is typical for turmeric. The remaining 30% of the

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supercritical extract is composed of non-volatile lipids.

9. That the more polar curcuminoids are present in the supercritical extract only in trace amounts. In particular, curcumin is typically present in an amount of 0.15% by weight in the supercritical extract, while the demethoxycurcumin and bisdemethoxycurcumin isomers are practically undetectable in the supercritical extract.

10. That the supercritical extract has some efficacy related to anti-inflammatory, anti-mutagenic and anti-microbial conditions, which is not related to the presence of curcuminoids.

11. That the hydroalcoholic extract has low amounts of the lipophilic constituents, but high amounts of curcuminoids. The amount of curcuminoids may be 25-50% by weight in a crude extract of turmeric, but if enriched as claimed in the '415 patent by crystallization, the curcuminoids should be present in an amount higher than 90% by weight, with only trace lipophilic constituents.

12. That the difference in extracts is also apparent from their physical characteristics. The curcuminoid product of the

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'415 patent is a powder with a melting range between 180 and 185°C while the supercritical extract is a clear liquid.

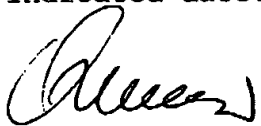
13. It is, therefore, my opinion that one of ordinary skill in the art would not be lead to modify or improve the '415 patent in an attempt to achieve the claimed invention based on the differences in the types of extracts as discussed herein.

14. All statements made herein of my own knowledge are true. All statements made herein upon information and belief are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both, under the provisions of 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing therefrom.

15. Further, declarants sayeth naught.

16. WITNESS my signature below in the indicated date.

Nov. 17, 2003


Dr. Karl-Werner Quirin